FDA at a Glance

FDA FOOD SAFETY MODERNIZATION ACT

Key Revisions: Proposed Rule on Foreign Supplier Verification Programs

Based on FDA outreach efforts and public comment, the FDA is proposing revisions to its proposed rule on foreign supplier verification programs intended to provide more flexibility in determining appropriate verification measures based on food and supplier risks. The agency is accepting comments on the revisions for 75 days after the publication date. The FDA published the original proposed rule on July 29, 2013, and the comment period closed on Jan. 27, 2014; no additional comments are being accepted on the original proposed rule. The FDA will accept comments on the revised provisions while continuing to review comments already received on the original proposed rule. Here is a summary of the key revisions.

1. **Hazard analysis**
   - The FDA is proposing a more comprehensive evaluation of food and supplier risks by combining the proposed requirement that an importer conduct a compliance status review of each food to be imported and each foreign supplier being considered, with the proposed requirement than an importer analyze the hazards in each food. The FDA is also expanding the factors that must be considered. (The compliance review would assess whether the food or supplier has been in violation of FDA regulations.)
     - Commenters felt that the FDA was putting too much emphasis on hazard analysis and the supplier's regulatory compliance in deciding what supplier verification measures are needed, while overlooking important supplier risk considerations.
   - This broader evaluation of risks would require importers to consider such factors as
     - the nature of hazards in food,
     - the entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier's ingredient supplier,
     - the foreign supplier's procedures, processes and practices related to food safety,
     - applicable U.S. food safety regulations and information regarding the foreign supplier's compliance with those regulations, and
     - the foreign supplier's food-safety performance history.
   - FDA is asking for input on whether importers should be required to consider hazards that may be intentionally introduced for purposes of economic gain as part of its hazard analysis.

2. **Supplier verification**
   - The FDA is proposing a provision for required supplier verification activities that is a hybrid of the two options presented in the originally proposed rule.
     - Under Option 1 of the original proposal, annual on-site auditing of foreign suppliers would have been required when the foreign supplier controls the hazard in a food and the hazard is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard). In other circumstances, the importer could determine an appropriate verification activity from among several specified methods, which would include on-site auditing, sampling and testing,

review of supplier food safety records, and any other appropriate method.
    - Under Option 2, on-site auditing would not have been mandatory under any circumstances. Instead, the importer would determine the appropriate verification activity – based on the risk presented by the hazard, the probability that exposure will result in serious harm or death, and the food and supplier's compliance status.
- The approach that the FDA is proposing would provide importers the flexibility to determine appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods.
    - When there is reason to believe that a hazard will cause serious injuries or deaths, a clear, rigorous verification standard is required in the form of annual on-site auditing of the supplier. Importers would be allowed to use a different approach (possibly including less frequent auditing) only if they can establish that it will provide adequate assurance that the hazard is controlled.

3. Consistency with other proposed FSMA rules

- To make the proposed FSVP rule consistent with the revisions to the proposed rules on preventive controls for human food and preventive controls for animal Food, FDA revisions include
    - changing the definitions of "very small importer" and "very small foreign supplier" to having no more than $1 million in annual food sales rather than the previously proposed limit of $500,000 in annual food sales, and
    - deeming that importers that operate food facilities in compliance with any potential supplier verification provisions that may be included in the preventive controls rules are in compliance with any parallel FSVP requirements to avoid duplicative regulations.

Compliance Dates

- In general, the compliance date would be 18 months after publication of the final FSVP regulations. There would be some exceptions.
    - For the importation of food that is also subject to the preventive controls and produce safety rules, the importer would be required to comply with FSVP regulations six months after the foreign supplier is required to comply with preventive controls or produce safety regulations. The compliance dates for those regulations vary, depending on the rule and size of the operation.

More Information

- Visit http://www.regulations.gov/
- FDA's Food Safety Modernization Act page at www.fda.gov/FSMA